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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,510	05/26/2000	MICHAEL TSCHOPE	P100564-0000	7619

4372 7590 06/26/2003

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WASHINGTON, DC 20036

EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/26/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/508,510**

Applicant(s)  
**Tschope et al.**

Examiner  
**First Last**

Art Unit  
**1234**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 7, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-23, and 25-31 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17-23, and 25-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

1. Claims 24 has been canceled previously. Claims 15-16 have been canceled in Paper No.17 (5/7/03). Claims 4, 6-8, 10, 13-14, 21-23, 26, amended claims 1-3, 5, 9, 11-12, 17-20, 25 (Paper No. 17, 5/7/03), and new claims 27-31 (Paper No. 17, 5/7/03), are under consideration.
2. Receipt of applicant's arguments and amendments filed in Paper No. 17 (5/7/03) is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 17, 5/7/03:
  - (i) the substitute specification has been entered; and
  - (ii) the rejection of claims 1-23, 25-26 under under 35 U.S.C. § 112, first paragraph for new matter.
4. Applicant's arguments filed in Paper No. 17 (5/7/03), have been fully considered but were persuasive in part. The issues remaining and new issues, are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112, second paragraph***

6. Claims 1-23, 25-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1, 3, 26 remain rejected for reciting "in vitro biological activity" which includes in vitro antiviral, antiproliferative and immunomodulatory activities determined by assays which are used to assess the biological activity of IFN- $\beta$ . However, it is unclear which of these activities is being retained in the instantly claimed formulation. Applicants argue that one of ordinary skill in the art would clearly know the meaning of the term "biological activity". However, contrary to applicants arguments, in the instant specification the method for determining the biological activity after the storage period chosen was measured by the method of inhibiting the cytopathic effect of a virus (see new claims 30-31). Therefore, since this is the biological activity defined in the specification, the metes and bounds of the term "biological activity" recited in the claims is unclear. Applicants can obviate this rejection by reciting the biological activity for which there is support in the instant specification.

Regarding claim 1, the phrase "optionally, at least one...." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP. § 2173.05(d).

Claims 2, 4-14, 17-23, 27-31 are rejected under 35 U.S.C. 112, first paragraph, insofar as they depend on the above claims for this newly added limitation.

***Claim rejections-35 USC § 102***

7. Claims 1-2, 4-8, 13-14, 21-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0529300.

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This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (Paper No. 16, 2/7/03).

Applicant argues that claim 1 has been amended to recite a formulation consisting essentially of human interferon- $\beta$  in a concentration of up to  $25 \times 10^6$  U/ml, a buffer for buffering in a pH range of 5 to 8, and optionally, at least one physiologically acceptable preservative. Applicants argue that thus the presence of stabilizers such as HSA or PVP is excluded. However, the recitation of the new limitation "optionally" in claim 1 encompasses a formulation of recombinant IFN- $\beta$  with human serum albumin as recited in the amended claim, which limitation is anticipated by Examples 2, 4-5 of the prior art reference. Therefore, the reference anticipates the above claims.

***Claim rejections-35 USC § 103***

8. Claims 1-14, 17-23, 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0529300 in view of Patel (U.S. Patent No. 5,358,708).

This rejection is maintained for reasons of record set forth at pages 7-8 of the previous Office action (Paper No. 16, 2/7/03).

Applicant argues that the Patel reference teaches IFN- $\alpha$ -2b formulations, but does not teach IFN- $\beta$  formulations. If the Patel reference specifically taught IFN- $\beta$  formulations, this rejection would be a 35 U.S.C. 102 rejection rather than a 35 U.S.C. 103 rejection. Applicants argue that based on any teaching either in Patel or in the art, there would be no reasonable expectation of success of such a formulation. Furthermore, Applicants argue that low concentration protein solutions had a known tendency to produce instability and it was believed that they needed to be

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stabilized by the addition of stabilizers. However, contrary to Applicants arguments, the recitation of the term “optionally” meets this limitation.

Applicants argue that Figure 1 of the reference indicates that IFN- $\alpha$  shows a significant decrease in biological activity after two weeks storage, despite the addition of methionine or histidine. However, instant claim 3 recites “80% of an initial biological activity” which is indicated in Figure 1 (above 80% of the biological activity is maintained).

With respect to the new limitations “oral, parenteral or ophthalmological administration”, one of skill in the art would be motivated to administer the pharmaceutical composition in a form suitable for such administration for the intended use of the pharmaceutical composition. Furthermore, with respect to the limitations in new claims 30-31, one of skill in the art would be motivated to measure the biological activity after the storage period chosen by using the standard method of inhibiting the cytopathic effect of a virus. Therefore, the references render obvious the claims.

### ***Conclusion***

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
May 28, 2003